

**RICHARD JANNARONE and SUSAN  
JANNARONE,**  
  
**Plaintiffs,**  
  
**v.**  
  
**SMITHKLINE BEECHAM CORP.  
d/b/a GLAXOSMITHKLINE, GSK  
BIOLOGICALS NA, and  
GLAXOSMITHKLINE  
PHARMACEUTICALS RESEARCH  
AND DEVELOPMENT**  
  
**Defendants.**

1. This is a pharmaceutical product liability case. On or about November 28, 2012, plaintiffs Richard Jannarone and Susan Jannarone (“Plaintiffs”) filed a complaint (“Complaint”) in the Court of Common Pleas, Philadelphia County, Case No: 121102856. A true and correct copy of the Complaint is attached as Exhibit A to this Notice of Removal. According to the Complaint, Plaintiffs allege, *inter alia*, that Richard Jannarone “sustained severe and permanent personal injuries,” including but not limited to malignant prostate cancer, as a result of defendants’ alleged conduct in connection with the “manufacture, advertising, promotion, distribution, and/or sale of Avodart.” Complaint ¶¶ 36, 34.

2. As explained below, this Court has original subject matter jurisdiction over this civil action pursuant to 28 U.S.C. § 1332, and the action may be removed to this Court under 28 U.S.C. § 1441 because (i) there is complete diversity of citizenship between Plaintiffs and defendants, and (ii) the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

### **DIVERSITY OF CITIZENSHIP**

3. The Complaint names “SmithKline Beecham Corp. d/b/a GlaxoSmithKline,” “GSK Biologicals NA,” and “GlaxoSmithKline Pharmaceuticals Research and Development” as defendants.

#### **Defendant GlaxoSmithKline LLC (“GSK LLC”), formerly SmithKline Beecham Corporation d/b/a GlaxoSmithKline**

4. GSK LLC is, and at the time the Complaint was filed was, a citizen of the State of Delaware for purposes of diversity jurisdiction.

5. GSK LLC is a limited liability company. The sole member of GSK LLC is, and at the time the Complaint was filed was, GlaxoSmithKline Holdings (Americas) Inc. (“GSK Holdings”).

6. For purposes of diversity jurisdiction, determining the citizenship of GSK LLC is a two-step process. First, under the Third Circuit’s ruling in *Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 420 (3d Cir. 2010), the citizenship of a limited liability company, such as GSK LLC, is determined by looking to the citizenship of the limited liability company’s members — in this case, GSK Holdings, a corporation. Second, under the Supreme Court’s ruling in *Hertz Corp. v. Friend*, 130 S. Ct. 1181, 1185-86 (2010), a corporation is a citizen of the state in which it is incorporated and the state in which it has its principal place of business, as determined by the “nerve center” test.

7. Applying this two-step analysis here, GSK LLC is solely a citizen of Delaware. First, under *Zambelli*, GSK LLC's citizenship is determined by the citizenship of its sole member, GSK Holdings. Second, under *Hertz*, GSK Holdings is solely a citizen of Delaware: GSK Holdings is incorporated under Delaware law; GSK Holdings' officers direct, control, and coordinate the work of GSK Holdings primarily in Delaware; GSK Holdings' "nerve center" is therefore in Delaware. Because Delaware is both GSK Holdings' state of incorporation and the location of its nerve center, GSK Holdings is solely a citizen of Delaware. Therefore, GSK LLC also is solely a Delaware citizen.

8. At least three courts have followed this two-step analysis and have concluded that GSK LLC is solely a citizen of Delaware. *Johnson v. SmithKline Beecham Corp. et al.*, No. 11-5782, 2012 U.S. Dist. LEXIS 44315, at \*7 (E.D. Pa. Mar. 29, 2012) ("Because GSK LLC's sole member is Holdings, its citizenship is determined by that of Holdings."); *id.* at \*19 ("Holdings's nerve center is where its ownership decisions are made: Wilmington. Accordingly, Holdings and LLC are Delaware citizens."); *White v. SmithKline Beecham Corp.*, No. 10-2241, 2010 U.S. Dist. LEXIS 79520, \*5-9 (E.D. Pa. Aug. 5, 2010) (holding that GSK LLC is a citizen of Delaware, the State of the "nerve center" of its sole member, GSK Holdings); *Hoch v. Eli Lilly & Co.*, 736 F. Supp. 2d 219, 221 (D.D.C. 2010) (reasoning that "[t]he plaintiffs mistakenly treat GSK LLC as a corporation, applying the nerve center test to GSK LLC rather than to its sole member, GSK Holdings" and concluding that there is "sufficient evidence that GSK Holdings' nerve center is in Delaware").<sup>1</sup>

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<sup>1</sup> There is a split of authority as to the citizenship of GSK LLC. Although the courts in *White*, *Johnson*, and *Hoch* held that GSK LLC is solely a citizen of Delaware, some courts in this district have found that GSK LLC is a citizen of Pennsylvania. See, e.g., *Brewer v. SmithKline Beecham Corp.*, 774 F. Supp. 2d 721, 732 (E.D. Pa. 2011); *Maldonado v. SmithKline Beecham* (continued...)

9. GSK LLC was not at the time of the commencement of this action or at any time thereafter a citizen of the State of Texas or of the State of Pennsylvania.

**Defendant Corixa Corporation, named as “GSK Biologicals NA”**

10. GSK Biologicals NA is, and at the time the Complaint was filed was, a “doing business as” name of Corixa Corporation (“Corixa”). Corixa is, and at the time the Complaint was filed was, a Delaware corporation with its principal place of business in Pennsylvania. Accordingly, Corixa, named as GSK Biologicals NA, is a citizen of the States of Delaware and Pennsylvania for purposes of diversity jurisdiction. However, because GSK Biologicals NA was never involved in the development, manufacture, marketing, or sale of the pharmaceutical product at issue in this action, there is no possible recovery (reasonable or otherwise) from Corixa or GSK Biologicals NA in this action. Therefore, Corixa, named as GSK Biologicals

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*Corp.*, No. 11-2812, 2011 U.S. Dist. LEXIS 142578 (E.D. Pa. Dec. 12, 2012); *Murray v. SmithKline Beecham Corp. et al.*, No. 11-3510, 2012 U.S. Dist. LEXIS 47029, at \*3 (E.D. Pa. Mar. 29, 2012); *Yeatts v. SmithKline Beecham Corp. et al.*, No. 11-6711, 2012 U.S. Dist. LEXIS 46979, at \*6-7 (E.D. Pa. Mar. 29, 2012); *Patton ex rel. Daniels-Patton v. SmithKline Beecham Corp.*, CIV.A. 11-5965, 2011 WL 6210724 (E.D. Pa. Dec. 14, 2011). However, the decisions in those cases are flawed for several reasons. First, to determine GSK Holdings’ principal place of business, the courts wrongly “look[ed] to the ‘nerve center’ of the limited liability company” rather than GSK Holdings. *See, e.g., Brewer*, 774 F. Supp. 2d at 722, 728-29 (emphasis added); *Maldonado*, 2011 U.S. Dist. LEXIS 142578 at \*25. In addition, the courts improperly disregarded the distinction between GSK Holdings and GSK LLC. It is well-established in this Circuit that where, as here, corporate formalities are maintained, citizenship determinations must be based solely on the attributes of the entity in question. *See Quaker State Dyeing & Finishing Co., Inc. v. ITT Terryphone Corp.*, 461 F.2d, 1140, 1142 (3d Cir. 1972) (“[W]here the corporate separation between a parent and a subsidiary, though perhaps merely formal, is real and carefully maintained, the separate place of business of the subsidiary is recognized in determining jurisdiction, even though the parent exerts a high degree of control through ownership or otherwise.” (internal quotation marks omitted)); *see also, e.g., Johnson*, 2012 U.S. Dist. LEXIS 44315, at \*15 (declining to follow *Brewer* and *Maldonado*, rejecting the argument that the activities of GSK LLC can be used to determine GSK Holdings’ citizenship, and reasoning that “[t]he law suggests just the opposite”) (collecting cites). On May 22, 2012, The Third Circuit granted permission to appeal the decision in *Johnson* and therefore this split of authority may be resolved in the near future. *See* Order dated May 22, 2012 in *Johnson v. SmithKline Beecham Corp., et al.*, 3d Cir. No. 12-2561.

NA, is fraudulently joined and its citizenship must be disregarded for purposes of diversity jurisdiction. *See, e.g., In re Consol. Fen-Phen Cases*, 03 CV 3081 (JG), 2003 WL 22682440 (E.D.N.Y. Nov. 12, 2003) (disregarding the citizenship of a defendant who was fraudulently joined to a pharmaceutical product liability action because it did not market or sell the pharmaceutical product at issue).

11. Corixa, named as GSK Biologicals NA, was not at the time of the commencement of this action or at any time thereafter a citizen of the State of Texas.

**GlaxoSmithKline Pharmaceuticals Research and Development**

12. Upon information and belief, there is no entity by the name of “Glaxosmithkline Pharmaceuticals Research and Development” as named in the Complaint.

13. Upon information and belief, no entity by the name of “Glaxosmithkline Pharmaceuticals Research and Development” was at the time of the commencement of this action or at any time thereafter a citizen of the State of Texas or of the State of Pennsylvania.

**Plaintiffs**

14. Plaintiffs reside in and are, and at the time the Complaint was filed were, citizens of the State of Texas for purposes of diversity jurisdiction. Complaint ¶ 1.

15. There is complete diversity among the parties because Plaintiffs are citizens of Texas, and none of the defendants are citizens of that state.

**AMOUNT IN CONTROVERSY**

16. Plaintiffs seek, *inter alia*, compensatory damages, pain and suffering, and punitive and/or exemplary damages and allege that Richard Jannarone “sustained severe and permanent personal injuries, including but not limited to:”

a. Prostate cancer;

- b. Substantial conscious pain and suffering, both physical and emotional in nature;
- c. Significant expenses for medical care and treatment;
- d. Lost wages and earnings; and Severe pecuniary loss[;]
- f. The need for continued healthcare services, medical and related expenses; and
- g. Diminished capacity for the enjoyment of life and a diminished quality of life.

Complaint ¶ 36.

17. Although the Complaint does not demand a specific dollar amount in damages, the preponderance of the evidence demonstrates that the matter in controversy exceeds \$75,000, exclusive of interest and costs. *See* 28 U.S.C. § 1446(c)(2)(B) (requisite amount in controversy may be demonstrated by “preponderance of the evidence”).

18. In cases involving allegations of prostate cancer, juries in Pennsylvania have awarded plaintiffs in excess of \$75,000 in damages. *See, e.g., Hines v. Kosseim, M.D.; Penn Center for Primary Care*, JVR No. 436524, 2005 WL 4169266 (Unknown Pa. State Ct.) (\$2,573,793 jury verdict in favor of plaintiff alleging, *inter alia*, failure to timely diagnose prostate cancer); *Roberson v. Nelson*, 2001 WL 36383209 (Pa.Com.Pl.) (\$1,000,000.00 jury verdict in favor of plaintiff for, *inter alia*, negligent failure to promptly diagnose prostate carcinoma); *Gionta v. Zida*, JVR No. 55504, 1990 WL 460106 (Pa.Com.Pl.) (\$758,777 jury verdict in favor of plaintiff alleging that he suffered prostate cancer after the defendant family practitioner neglected to perform a routine examination to check for symptoms).

19. Accordingly, this Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

**FORUM DEFENDANT RULE**

20. Section 1441(b)(2) provides that actions premised on the Court's diversity jurisdiction "may not be removed if any of the parties in interest *properly joined and served* as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b)(2) (emphasis added).

21. The Third Circuit has admonished that, "[i]f the language of the statute is plain, the sole function of the court is to enforce the statute according to its terms." *Abdul-Akbar v. McKelvie*, 239 F.3d 307, 313 (3d Cir. 2001); *see also Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("When the words of a statute are unambiguous . . . 'judicial inquiry is complete.'" (citation omitted)). Moreover, although courts generally hold that the removal statutes are to be strictly construed, the Third Circuit has recently held that "the general rule that removal statutes are to be construed strictly is not sufficient to displace the plain meaning of [those statutes]." *Delalla v. Hanover Ins.*, 660 F.3d 180, 189 (3d Cir. 2011).

22. Because the plain language of section 1441(b)(2) requires both proper joinder and service, courts have held that "the presence of an unserved defendant with residence in the forum state does not defeat removal where there is complete diversity of citizenship." *Vanderwerf v. Glaxosmithkline, PLC.*, CIV.A. 05-1315, 2005 WL 6151369 (E.D. Pa. May 5, 2005). *See also Banks v. Kmart Corp.*, No. 12-607, 2012 WL 707025, at \*2 (E.D. Pa. Mar. 6, 2012) ("Under the plain language of the removal statute, removal is barred only if a defendant is a forum defendant and has been 'properly joined and served.'" (citation omitted)).

23. As of the time of this filing, none of the defendants have been served with the Complaint or with service of process. Accordingly, 28 U.S.C. § 1441(b)(2) does not preclude removal.<sup>2</sup>

24. In addition, the presence of Corixa, named as GSK Biologicals NA and having its principal place of business in Pennsylvania, does not defeat removal for an additional and independent reason. As set forth above in paragraph 10, GSK Biologicals NA was never involved in the development, manufacture, marketing, or sale of the pharmaceutical product at issue in this action. As a result, there is no possible recovery (reasonable or otherwise) from Corixa or GSK Biologicals NA in this action. Therefore, Corixa, named as GSK Biologicals NA, has been fraudulently joined and its citizenship must be disregarded for purposes of diversity jurisdiction.

#### **OTHER PROVISIONS**

25. The Complaint was filed on November 28, 2012. GSK LLC has not been served with a copy of the Complaint. This Notice of Removal is timely filed under 28

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<sup>2</sup> The Federal Courts Jurisdiction and Venue Clarification Act of 2011 made various amendments to the removal statute. Nevertheless, with respect to the limitation on the removal of cases naming an in-forum defendant Congress left intact the requirement that to bar removal, such defendants must be “properly joined and served as defendants.” “[B]y retaining the ‘properly joined and served language,’ the amendment reinforces the conclusion that Congress intended for the plain language of the statute to be followed.” *Munchel v. Wyeth LLC*, No. 12-906-LPS, 2012 WL 4050072, at \*4 (D. Del. Sept. 11, 2012). *See also Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230, 239-40 (2009) (“Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.”) (internal quotation marks omitted); *Regal Stone Ltd. v. Longs Drug Stores California, L.L.C.*, No 11-4540 SC, 2012 WL 685756, at \*4 (N.D. Cal. March 2, 2012) (“[I]t is well-settled that where Congress amends part of a statute and leaves another part unchanged, a court must interpret Congress’s inaction as satisfaction with the unamended portion, or at least tolerance of its inadequacies. . . . [Thus,] [t]he Court is therefore bound to take Congress’s preservation of § 1441’s ‘properly joined and served’ language as an endorsement”) (citations omitted).

U.S.C. § 1446(b). *See Delgado v. Shell Oil Co.*, 231 F.3d 165, 177 (5th Cir. 2000) (“We read § 1446(b) and its ‘through service or otherwise’ language as consciously reflecting a desire on the part of Congress to require that an action be commenced . . . before removal, but not that the defendant have been served.”).

26. The United States District Court for the Eastern District of Pennsylvania is the federal judicial district encompassing the Court of Common Pleas of Philadelphia County, Pennsylvania, where Plaintiffs originally filed this suit such that this is the proper federal district for removal of this case to federal court. 28 U.S.C. § 1441(a); 28 U.S.C. § 118(a).

27. To date, no process, pleadings, papers or orders have been served upon GSK LLC or the non-removing defendants. Accordingly, there are no such documents to submit with this Notice of Removal pursuant to 28 U.S.C. § 1446(a).

28. GSK LLC has not been served, and upon information and belief, there has been no service upon the other named defendants either. Furthermore, Corixa, named as GSK Biologicals NA, has been fraudulently joined, and, upon information and belief, there is no entity by the name of “GlaxoSmithKline Pharmaceuticals Research and Development.” Accordingly, consent to this removal is not required by 28 U.S.C. § 1446(b)(2). *See Brown v. Jevic*, 575 F.3d 322, 327 (3d Cir. 2009) (“a defendant who has not been served need not consent to removal”); *Balazik v. County of Daupin*, 44 F.3d 209, 213 n.4 (3d Cir.1995) (“fraudulently joined” defendants need not join in removal).

29. Pursuant to 28 U.S.C. § 1446(d), GSK LLC will promptly file a copy of this Notice of Removal with the Prothonotary of the Court of Common Pleas of Philadelphia County, Pennsylvania, and will serve a copy of same upon counsel for Plaintiffs.

30. By filing this Notice of Removal, GSK LLC does not waive any jurisdictional or other defenses that might be available to it.

31. GSK LLC reserves the right to amend or supplement this Notice of Removal.

WHEREFORE, Defendant GSK LLC hereby removes this action from the Court of Common Pleas of Philadelphia County, Pennsylvania, to the United States District Court for the Eastern District of Pennsylvania pursuant to 28 U.S.C. §§ 1441 and 1446, and states that no further proceedings may be had in the state action.

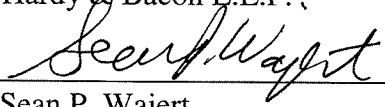
Dated: December 6, 2012

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Respectfully submitted,

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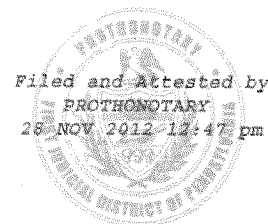
# **EXHIBIT A**

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**IN THE COURT OF COMMON PLEAS  
PHILADELPHIA COUNTY**

RICHARD JANNARONE and SUSAN JANNARONE,  
*Plaintiffs,*

v.

SMITHKLINE BEECHAM CORP. d/b/a  
GLAXOSMITHKLINE,  
GSK BIOLOGICALS NA, and  
GLAXOSMITHKLINE PHARMACEUTICALS  
RESEARCH AND DEVELOPMENT

*Defendants.*

: NOVEMBER TERM 2012

: No. \_\_\_\_\_

: **JURY TRIAL DEMANDED**

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Plaintiffs RICHARD JANNARONE and SUSAN JANNARONE, by and through their undersigned attorneys, hereby allege and state the following causes of action:

**PARTIES**

1. Plaintiffs Richard and Susan Jannarone are residents and citizens of Grapevine, Texas, residing at 925 South Main Street, Unit 3356, Grapevine, TX 76051.

2. At all times relevant, plaintiffs Richard and Susan Jannarone were and are husband and wife.

3. Defendant SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE is a corporation formed in the State of Delaware, with its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania 19101. Defendant does business in Pennsylvania and with many Pennsylvania individuals, firms and corporations, and has substantial contacts with the Commonwealth of Pennsylvania, specifically Philadelphia County, Lancaster County (with a pharmaceutical manufacturing plant at GSK Biologicals NA, 206 N Biddle Street, Marietta, PA 17547) and Montgomery County (with a business location at GlaxoSmithKline Pharmaceuticals Research and Development, 709 Swedeland Road, King of Prussia, PA 19406).

4. Defendant GSK BIOLOGICALS NA is a Pennsylvania corporation with its principal place of business located at 206 N Biddle Street, Marietta, PA 17547. Defendant does business in Pennsylvania and with many Pennsylvania individuals, firms and corporations, and has substantial contacts with the Commonwealth of Pennsylvania, including Philadelphia County, Lancaster County and Montgomery County.

5. Defendant GLAXOSMITHKLINE PHARMACEUTICALS RESEARCH AND DEVELOPMENT is a Pennsylvania corporation with its principal place of business located at 709 Swedeland Road, King of Prussia, PA 19406. Defendant does business in Pennsylvania and with many Pennsylvania individuals, firms and corporations, and has substantial contacts with the Commonwealth of Pennsylvania, including Philadelphia County, Lancaster County and Montgomery County.

6. Defendants are hereinafter collectively referred to as "GSK".

7. At all times relevant hereto, upon information and belief, either directly or indirectly through third parties, GSK engaged in the business of designing, testing, manufacturing, labeling, licensing, marketing, distributing, promoting, and/or selling the drug called Avodart.

8. At all times relevant hereto, upon information and belief, GSK engaged in the business of designing, testing, manufacturing, labeling, licensing, marketing, distributing, promoting and/or selling prescription drugs, including Avodart, and in pursuance of this business, transacted business within the Commonwealth of Pennsylvania and the County of Philadelphia, and contracted for goods and services in the Commonwealth of Pennsylvania and the County of Philadelphia.

#### **JURISDICTION AND VENUE**

9. This Court has jurisdiction over this action by virtue of GSK being subject to personal jurisdiction in this Court because GSK transacts business in the Commonwealth of Pennsylvania and the County of Philadelphia, has committed torts within the Commonwealth of Pennsylvania and the County of Philadelphia (as discussed below), and its acts or omissions giving rise to Plaintiff Richard Jannarone's claims occurred in the Commonwealth of Pennsylvania and the County of Philadelphia, and/or caused injury in the Commonwealth of Pennsylvania and the County of Philadelphia.

#### **FACTS REGARDING AVODART**

10. GSK introduced Avodart to treat symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate gland.

11. At all times relevant, GSK was responsible for, or involved in, designing, testing, manufacturing, labeling, licensing, marketing, distributing, promoting, and/or selling Avodart.

12. Benign prostatic hyperplasia (BPH) is an increase in size of the prostate.

13. BPH can lead to various symptoms such as urinary hesitancy, frequent urination, painful urination, increased risk of urinary tract infections, and urinary retention.

14. BPH does not cause prostate cancer nor increase the risk of prostate cancer.

15. On November 20, 2001, the U.S. Food and Drug Administration (FDA) approved the drug Avodart to be marketed and sold in the United States by GlaxoSmithKline.

16. The applicable FDA Approval Letter said that Avodart was initially indicated “for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate gland.”

17. Avodart operates by inhibiting the conversion of testosterone to dihydrotestosterone (DHT).

a. DHT is the androgen primarily responsible for the initial development and subsequent enlargement of the prostate gland.

b. Testosterone is converted to DHT by the intracellular enzyme 5 alpha-reductase. This enzyme exists as type 1 and type 2 isoenzymes.

c. Avodart contains dutasteride, which forms a stable enzyme complex with both 5 alpha-reductase isoforms, thereby inhibiting the conversion to DHT.

18. Avodart’s prescribing information warned that dutasteride reduces total serum prostate-specific antigen (PSA) concentration.

19. PSA is present in small quantities in the serum of men with healthy prostates, but is often elevated in the presence of prostate cancer. Elevated PSA levels give cause for a biopsy of the prostate to determine if cancer cells are present.

20. Prostate cancer diagnosis includes Gleason grading of the cancer cells on a scale of 2–10, which allows for prediction of the prognosis and appropriate treatment.

21. Most prostate cancers detected have a Gleason score of less than 6, which is considered to be low-grade cancer. Low-grade cancers are well-differentiated, less aggressive tumors that would be unlikely to cause morbidity if left untreated.

22. A Gleason score of 7–10 indicates high-grade prostate cancer and describes less differentiated, more aggressive tumors.

23. On March 26, 2010, GSK submitted a supplemental New Drug Application (sNDA 021319/024) to the FDA with a proposed indication: “Reduction in the risk of prostate cancer in men at increased risk of developing the disease.”

24. On October 25, 2010, GSK submitted a modification to sNDA 021319/024. The proposed indication provided: “Avodart is indicated for reduction in the risk of prostate cancer in men at increased risk of developing disease, defined as those who have had a prior negative biopsy due to clinical concern and have an elevated serum prostate-specific antigen (PSA).”

25. On December 1, 2010, the FDA Oncologic Drugs Advisory Committee (ODAC) held a meeting to discuss sNDA 021319/024, among other things.

- a. This meeting provided discussion on GSK’s REDUCE (REduction by DUtasteride of prostate Cancer Events) trial.
- b. The purpose of the REDUCE trial was to evaluate, over the course of 4 years, the effect of dutasteride on men at increased risk of developing prostate cancer. Such men were defined as those who have had a prior negative biopsy due to clinical concern and to have an elevated serum PSA.

- c. The study's evaluation was based on comparison of men taking dutasteride with men taking a placebo.
- d. The study found that while there was a decreased detection of cancer incidence, this decrease was almost entirely due to decrease in detection of low-grade cancer.
- e. However, while there was a decrease in detection of low-grade cancer, there was also a significant increase in the incidence of high-grade cancer, specifically with Gleason scores of 8–10.

26. On December 1, 2010 the majority of the ODAC voted that the dutasteride risk-benefit was not favorable “for reduction in the risk of prostate cancer in men at increased risk of developing the disease, defined as those who have had a prior negative biopsy due to clinical concern and have an elevated serum PSA.”

27. On June 9, 2011, the FDA issued a safety communication regarding the 5-alpha reductase inhibitor (5-ARI) class of drugs, which includes dutasteride.

- a. The FDA announced that it was “informing healthcare professionals that the Warnings and Precautions section of the labels for the 5-alpha reductase inhibitor (5-ARI) class of drugs has been revised to include new safety information about the increased risk of being diagnosed with a more serious form of prostate cancer (high-grade prostate cancer).”
- b. The announcement was “based on FDA’s review of two large, randomized controlled trials ... both trials showed an increased incidence of high-grade prostate cancer with finasteride and dutasteride treatment.”

28. Medical literature has since exposed the fact that taking Avodart is associated with a higher risk of high-grade cancer.

29. Upon information and belief, GSK knew or should have known that the use of Avodart would result in a higher risk of high-grade prostate cancer.

30. GSK failed to recognize the correlation between Avodart and the development of high-grade prostate cancer despite the wealth of scientific information available.

31. Upon information and belief, GSK knew or should have known about the correlation between the use of Avodart and high-grade prostate cancer, yet still promoted, sold, advertised, and marketed the use of Avodart for treatment of BPH.

**FACTS PERTAINING TO PLAINTIFF**

32. On or about October 10, 2008, Plaintiff Richard Jannarone began taking Avodart.

33. Plaintiff was prescribed Avodart for its intended purpose: the treatment of BPH.

34. Based upon testing, Plaintiff was diagnosed with malignant prostate cancer on or about December 29, 2009.

35. Plaintiff discovered the cause of his injury only after the FDA mandated that the risk of high-grade cancer be included on the label and instructions for Avodart.

36. As a result of the manufacture, marketing, advertising, promotion, distribution, and/or sale of Avodart to Plaintiff Richard Jannarone, Mr. Jannarone sustained severe and permanent personal injuries, including but not limited to:

- a. Prostate cancer;
- b. Substantial conscious pain and suffering, both physical and emotional in nature;
- c. Significant expenses for medical care and treatment;
- d. Lost wages and earnings; and

- e. Severe pecuniary loss.
- f. The need for continued healthcare services, medical and related expenses; and
- g. Diminished capacity for the enjoyment of life and a diminished quality of life.

37. GSK knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm caused by Avodart.

38. GSK intentionally concealed and/or recklessly failed to disclose to the medical community, the public (including Plaintiffs herein), and the FDA the potentially life-threatening side effects of Avodart, in order to ensure continued and increased sales.

39. GSK's intentional and/or reckless failure to disclose information deprived the Plaintiff of necessary information to enable him to weigh the true risks of using the subject product against its benefits.

40. The aforesaid conduct of GSK was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiffs herein, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish GSK and deter them from similar conduct in the future.

**COUNT I**  
**COMMON LAW FRAUD**

41. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

42. GSK's superior knowledge and expertise, their relationship of trust and confidence with the public, their specific knowledge regarding the risks and dangers of Avodart,

and their intentional dissemination of promotional and marketing information and advertisements about Avodart, for the purpose of maximizing sales, each give rise to the affirmative duty to meaningfully disclose and provide all material information about Avodart's risks and harms to consumers like Plaintiffs.

43. GSK made fraudulent affirmative and material misrepresentations and omissions, as statements of fact, with respect to Avodart in the following particulars:

- a. GSK represented through the labeling, advertising, marketing material, advertisements, and packaging that Avodart had been tested and was found to be safe and effective for the treatment of BPH;
- b. GSK knowingly omitted in the packaging for this product that Avodart users were at an increased risk of being diagnosed with high-grade prostate cancer, but knew or had reason to know that the product caused the condition; and
- c. GSK represented Avodart was safe, when, indeed, it was not.

44. GSK made affirmative misrepresentations and fraudulently, intentionally and/or recklessly concealed and suppressed material adverse information regarding the safety and effectiveness of Avodart.

45. These statements were untrue and were known by GSK to be untrue at the time GSK made the statements.

46. GSK made these misrepresentations and actively concealed adverse information at a time when GSK knew or had reason to know that Avodart had defects and was unreasonably dangerous and was not what GSK had represented to the consuming public, including Plaintiffs.

47. GSK omitted, suppressed and/or concealed material facts concerning the dangers and risks of injuries associated with the use of Avodart including, but not limited to: increased risk of high-grade prostate cancer.

48. Furthermore, GSK's purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Avodart in order to increase sales to consumers such as Plaintiff.

49. The representations and concealment were undertaken by GSK with an intent that Plaintiff would rely upon them, as he did.

50. GSK's representations and concealments were undertaken with the intent of defrauding and deceiving Plaintiff to induce and encourage the sale of Avodart.

51. GSK's fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

52. Plaintiff and Plaintiff's physician(s) justifiably relied on and were induced by GSK's misrepresentations, omissions, and/or active concealment of the dangers of Avodart in selecting the Avodart product.

53. Plaintiff and his physician(s) could not have discovered this information through ordinary means, and were entitled to and justified in relying upon GSK's superior skill, knowledge, representations, and omissions.

54. Plaintiff would not have purchased or used Avodart had Plaintiff and Plaintiff's physician(s) been aware of the increased risk of high-grade prostate cancer associated with administration of Avodart.

55. GSK acted with willful disregard for the safety of Plaintiff and placed profits over the safety of consumers, such as Plaintiff, to whom the product was sold for use.

56. GSK acted with callous disregard for the safety of Plaintiff.

57. Plaintiff was caused to suffer the grievous personal injuries and losses described herein as a result of GSK's willful misconduct.

58. GSK's conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish GSK and deter them from similar conduct in the future.

59. As a direct and proximate consequence of GSK's fraudulent acts, omissions, concealment, and misrepresentations, Plaintiff sustained serious personal injuries and related losses as detailed more fully herein.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

**COUNT II**  
**NEGLIGENT MISREPRESENTATION**

60. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

61. GSK represented and marketed Avodart as being safe and effective.

62. After GSK became aware of the risks of Avodart, GSK failed to communicate to the Plaintiff, other members of the general public, and the medical community that the administration of this drug increased the risk of high-grade prostate cancer.

63. Plaintiff brings this cause of action against GSK under the theory of negligent misrepresentation for the following reasons:

- a. GSK failed to warn the medical community and consumers such as Plaintiff, of the defective condition of Avodart, as manufactured and/or supplied by GSK;
- b. GSK, directly and through their agents, representatives, distributors and/or employees, negligently misrepresented material facts about Avodart in that GSK made such misrepresentations when GSK knew or reasonably should have known of the falsity of such misrepresentations.
- c. Alternatively, GSK made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;
- d. The above misrepresentations were made to the Plaintiff, as well as the general public;
- e. The Plaintiff and his healthcare providers justifiably relied on GSK's misrepresentations; and
- f. Consequently, the Plaintiff's ingestion of Avodart was to his detriment.

64. As a direct and proximate consequence of GSK's negligent misrepresentations, Plaintiff sustained serious personal injuries and related losses as detailed more fully herein

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief, as the Court deems proper.

**COUNT III**  
**NEGLIGENCE**

65. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

66. GSK had a duty to warn Plaintiff and Plaintiff's prescribing physician(s) or the medical community of the risks and/or defects about which it knew or should have known.

67. GSK failed to exercise reasonable care in providing warnings by failing to adequately warn Plaintiff, Plaintiff's prescribing physician(s), and/or the medical community of the risks of Avodart.

68. GSK failed to exercise reasonable care by not providing the Avodart manufactured and/or supplied by GSK to Plaintiff, Plaintiff's prescribing physician(s), and/or the medical community with proper warnings regarding all possible adverse side effects associated with the use of Avodart and the comparative severity, incidence, and duration of such adverse effects.

69. GSK failed to exercise reasonable care failing to adequately warn Plaintiff, Plaintiff's prescribing physician(s), and/or the medical community of the risks associated with exposure to Avodart to individuals.

70. The warnings and information accompanying Avodart did not accurately reflect the symptoms, scope, severity, or frequency of the potential side effects.

71. At a time when GSK knew or should have known of the risk of injury from Avodart, GSK failed to change the product's warnings so as to adequately warn users or consumers of the product as well as the medical community; failed to immediately recall or pull the product from retailers' shelves; and in fact continued to aggressively promote the product. As a direct result thereof, the Avodart manufactured and/or supplied by GSK was defective due to inadequate post-marketing warning and/or instructions.

72. Had Plaintiff been adequately warned by GSK of the dangers of Avodart, he would not have used Avodart and would not have been injured thereby.

73. Had Plaintiff's prescribing physician(s) been adequately warned by GSK of the dangers of Avodart, they would not have prescribed Avodart and Plaintiff would not have been injured thereby.

74. Had GSK adequately warned of the dangers of Avodart, Plaintiff could have received medical care to be treated for his injuries in a more prompt and effective manner, and Plaintiff's physicians would have been alerted to the problem and better prepared to identify and treat users of Avodart, including Plaintiff.

75. By reason of the foregoing, Plaintiff was and will be caused bodily injury, pain, suffering, and economic loss.

76. GSK acted with willful disregard for the safety of Plaintiff and placed profits over the safety of consumers, such as Plaintiff, to whom the product was sold for use.

77. GSK acted with callous disregard for the safety of Plaintiff.

78. Plaintiff was caused to suffer the grievous personal injuries and losses described herein as a result of GSK's negligence and/or willful misconduct.

79. As a direct and proximate consequence of GSK's negligence, Plaintiff sustained serious personal injuries and related losses as detailed more fully herein.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief, as the Court deems proper.

**COUNT IV**  
**PRODUCTS LIABILITY – DESIGN DEFECT**

80. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

81. At all times material to this action, GSK was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avodart.

82. Avodart is defective and unreasonably dangerous to consumers.

83. Avodart is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose, and/or its foreseeable risks exceed the benefits associated with its design and formulation.

84. At all times material to this action, Avodart was not safe and effective for the treatment of BPH, even though GSK directly and indirectly advertised, marketed, and promoted Avodart as such.

85. At all times material to this action, Avodart was not safe and was not suited for the purposes for which GSK, directly and indirectly, advertised, marketed, and promoted the drug at the time GSK designed, manufactured, distributed, and sold the drug and placed the drug in the stream of commerce.

86. Avodart was defective and unreasonably dangerous when it left control of GSK in one or more of the following manners:

- a. The risk associated with use of Avodart far outweighed the utility derived from using the drug;
- b. GSK failed to provide adequate warnings regarding the hazards associated with the use of Avodart;
- c. GSK's product was defectively designed and unreasonably dangerous in design and composition in that other drugs could achieve similar results without the risks presented by Avodart; and

d. Avodart failed to comply with express warranties that the product was safe and effective for human use.

87. In addition, at the time the subject product left the control of GSK, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of the Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of the Plaintiff's injuries without substantially impairing the product's utility.

88. As a direct and proximate result of the subject product's defective design, the Plaintiff suffered severe and permanent physical injuries.

89. As a direct and proximate consequence of GSK's defectively designed product, Plaintiff sustained serious personal injuries and related losses as detailed more fully herein.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief, as the Court deems proper.

**COUNT V**  
**PRODUCTS LIABILITY – FAILURE TO WARN**

90. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

91. GSK had a duty to warn Plaintiff of risks and/or defects about which it knew or should have known.

92. GSK failed to adequately warn Plaintiff or Plaintiff's prescribing physician(s) or the medical community of the risks of Avodart used by the Plaintiff.

93. The Avodart manufactured and/or supplied by GSK was unreasonably dangerous and defective because Avodart was not accompanied by proper warnings regarding all possible adverse side effects and the comparative severity, incidence, and duration of such adverse effects.

94. The Avodart manufactured and/or supplied by GSK was unreasonably dangerous and defective because Avodart was not accompanied by proper warnings regarding all possible adverse side effects to those individuals at increased risk of developing prostate cancer.

95. The warnings and information given to Plaintiff did not accurately reflect the symptoms, scope, severity, or frequency of potential side effects.

96. At all times relevant hereto, GSK intended for Avodart to be administered to members of the general public, including Plaintiff, and knew or should have known that the product would be administered to members of the general public, including Plaintiff.

97. Avodart was used by Plaintiff in a manner reasonably anticipated and foreseeable, and in the manner for which it was intended.

98. At all relevant times hereto, GSK was situated in the chain of commerce and transferred, sold, marketed, advertised, or distributed Avodart in the course of regular business.

99. At all relevant times hereto, Avodart was in the same or substantially the same, defective and unreasonably dangerous condition when put to its reasonably anticipated and foreseeable use, to wit:

- a. The Avodart drug was not properly manufactured;
- b. The Avodart drug was defectively designed;
- c. The Avodart drug did not perform as safely as an ordinary consumer/patient would expect; and

d. GSK failed to provide adequate warnings of the risks of Avodart, including (a) through (c) above.

100. GSK knew or should have known of the risk of injury from Avodart, but failed to provide adequate warnings to users or consumers of the product, as well as to the medical community; failed to immediately recall or pull the product from retailers' shelves; and in fact continued to aggressively promote the product. As a direct result thereof, Avodart manufactured was defective due to inadequate post-marketing warning and/or instructions.

101. Had GSK adequately warned Plaintiff and/or his prescribing physician(s) of the dangers of Avodart, Plaintiff would not have used Avodart and would not have been injured thereby.

102. Had GSK adequately warned Plaintiff and/or his prescribing physician(s) of the dangers of Avodart, Plaintiff could have received medical care to treat his injuries in a more prompt and effective manner, and Plaintiff's physicians would have been alerted to the problem and better prepared to identify and treat infected users of Avodart, including Plaintiff, more effectively.

103. As a direct and proximate consequence of GSK's defectively designed product, Plaintiff sustained serious personal injuries and related losses as detailed more fully herein.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief, as the Court deems proper.

**COUNT VI**  
**UNJUST ENRICHMENT**

104. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

105. As an intended and expected result of their conscious wrongdoing, GSK has profited and benefited from the purchase of Avodart by Plaintiff.

106. GSK has voluntarily accepted and retained these profits and benefits, derived from the Plaintiff and others, with full knowledge and awareness that, as a result of GSK's fraud and other conscious and intentional wrongdoing, Plaintiff did not receive a product of the quality, nature, or fitness that had been represented by GSK, or that Plaintiff, as a reasonable consumer, expected.

107. By virtue of the conscious wrongdoing alleged in this Complaint, GSK has been unjustly enriched at the expense of the Plaintiff, who in equity is entitled to, and hereby seeks the disgorgement and restitution of GSK's wrongful profits, revenue and benefits, to the extent, and in an amount, deemed appropriate by the Court; and such other relief as this Court deems just and proper to remedy GSK's unjust enrichment.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief, as the Court deems proper.

**COUNT VII**  
**BREACH OF IMPLIED WARRANTY**

108. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

109. GSK designed, manufactured, marketed, distributed, supplied, and sold the Avodart for the treatment of BPH.

110. At the time that GSK manufactured, marketed, distributed, supplied, and sold Avodart, GSK knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

111. The Plaintiff, individually and through his prescribing physician(s), reasonably relied upon the skill, superior knowledge and judgment of GSK.

112. The Plaintiff was administered, purchased, and used the subject product for its intended purpose.

113. Due to GSK's wrongful conduct as alleged herein, the Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after he used it.

114. Contrary to the implied warranty for the subject product, Avodart was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

115. As a direct and proximate result of GSK's breach of implied warranty, the Plaintiff suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

**COUNT VIII**  
**BREACH OF EXPRESS WARRANTY**

116. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

117. At all times relevant hereto, upon information and belief, GSK, by directly and indirectly advertising, marketing, and promoting Avodart for the treatment of BPH, and by placing this product in the stream of commerce knowing that Avodart would be prescribed to treat BPH based upon the GSK's representations, expressly warranted to all foreseeable users of

this product, including the Plaintiff, that Avodart was safe and effective for the treatment of BPH.

118. In manufacturing, distributing, selling, advertising, marketing, and promoting Avodart to all foreseeable users, including Plaintiff, GSK impliedly warranted that Avodart was safe and effective for the purposes for which it had been placed in the stream of commerce by GSK, including for the treatment of BPH, and that Avodart was reasonably safe, proper, merchantable, and fit for the intended purposes, including for the treatment of BPH.

119. At all times relevant hereto, Plaintiff relied upon the aforesaid express and implied warranties by GSK.

120. At all times relevant hereto, Plaintiff's use of Avodart was consistent with the purposes for which GSK directly and indirectly advertised, marketed, and promoted Avodart, and Plaintiff's use of Avodart was reasonably contemplated, intended, and foreseen by GSK at the time of the distribution and sale of Avodart by GSK, and therefore, Plaintiff's use of Avodart was within the scope of the above-described express and implied warranties.

121. GSK breached the aforesaid express and implied warranties because Avodart was not safe and effective for the prevention of BPH, and because Plaintiff's use of Avodart for the treatment of BPH caused or contributed to the injuries described herein.

122. As a direct and proximate result of GSK's breach of express warranty, the Plaintiff suffered severe and permanent physical injuries which are continuing in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

**COUNT IX**  
**LOSS OF CONSORTIUM**

123. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein.

124. As a result of Defendant GSK's negligence and other misconduct, Plaintiff Susan Jannarone has been deprived, and will continue to be deprived for an indefinite period of time into the future, of her husband's companionship, consortium and society.

125. As a further result of Defendant GSK's negligence and other misconduct, Plaintiff Susan Jannarone has incurred a loss of her own and has been caused to expend various sums of money for her husband's treatment and care, and has suffered the loss of the value of his services, some or all of which is expected to be permanent in nature.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs demand judgment against GSK on each of the above-referenced causes of action and as follows:

- a. Compensatory damages for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;
- b. Compensatory damages for any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the law;

- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of GSK who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff, in an amount to punish GSK and deter future similar conduct;
- d. Reasonable attorneys' fees where provided by law;
- e. Costs of these proceedings where provided by law; and
- f. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

Lopez McHugh, LLP



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And of counsel (for pro hac consideration):

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Law Offices of Sadaka Associates LLC  
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Attorneys for Plaintiffs

Dated: November 28, 2012

**VERIFICATION**

I hereby verify that I am counsel for the plaintiff and that the statements made in the foregoing Complaint are true and correct to the best of my knowledge, information and belief. The undersigned understands that the statements therein are made subject to the penalties of 18 Pa. C. S. § 4904 relating to unsworn falsification to authorities.

A handwritten signature in dark ink, appearing to read "Michael S. Katz", is written over a horizontal line.

Michael S. Katz

Dated: November 28, 2012

**CERTIFICATE OF SERVICE**


I hereby certify that I have on this day served a copy of the foregoing NOTICE OF REMOVAL by depositing a copy of the same in the U.S. Mail, first-class, postage prepaid, and addressed as follows:

Michael S. Katz  
Lopez McHugh, LLP  
1123 Admiral Peary Way, Quarters K  
Philadelphia, PA 19112

Mark T. Sadaka  
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*Attorneys for Plaintiffs*

This 6th day of December, 2012.

  
Sean P. Wajert